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10/590,136	11/22/2006	David C. Bloom	36689.259	2666

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EXAMINER	
HIBBERT, CATHERINE S	

ART UNIT	PAPER NUMBER
1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,136	BLOOM ET AL.	
	Examiner	Art Unit	
	CATHERINE HIBBERT	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,9,10,14,15,27-31,46-48,51,54 and 72-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,9,10,14,15,27-31,46-48,51,54 and 72-75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/20/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 2-7, 11-13, and 16-26 are currently cancelled. Claims 8, 32-45, 49-50, 52-53 and 55-71 were previously cancelled. Claims 1, 9-10, 14-15, 27-31, 47, 51, 54, and 72-75 are currently amended. Claims 1, 9-10, 14-15, 27-31, 46-48, 51, 54, and 72-75 are pending and under examination.

Election/Restrictions

Applicant's election without traverse of the species "the HSV-1 species of Herpesvirus as exemplified in SEQ ID NO:109" in the reply filed on 12 May 2010 is acknowledged.

Applicant's election without traverse of Group I (Claims 1-7, 9-31, 46-48, 51, 54 and 72-75) in the reply filed on 23 April 2009 is as previously acknowledged.

Information Disclosure Statement

The IDS filed on 20 November 2009 has been considered by the examiner.

Response to Amendments

All objections and rejections to currently canceled claims 2-7, 11-13, and 16-26 are moot.

All objections and rejections not repeated herein are withdrawn.

Applicants' Remarks filed 5/12/20 and 11/20/2009 have been fully considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 9-10, 14-15, 27-31, 46-48, 51, 54, and 72-75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The base claims 1 and 73 from which all other claims depend, recite the limitation in part (c) "operably positioned downstream of the LAT enhancer element". This limitation is unclear because the nucleotide parameters for the LAT enhancer element end at about nucleotide 120,471 but the second LAT insulatory/boundary region begins upstream of nucleotide 120,471 at position about 120,208. Therefore, it is unclear how the claimed polynucleotide can meet this limitation and what is intended to be embraced by this claim limitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 9-10, 14-15, 27-31, 46-48, 51, 54, and 72-75 are rejected under 35 U.S.C. 102(b) as being anticipated by Coffin and Latchman in "Eukaryotic Gene Expression Cassette and Uses Thereof" (WO 98/30707; published 16 July 1998; entire document; of record) for reasons of record and presented herein.

Currently amended claims read on an isolated polynucleotide that comprises:

(a) an HSV LAT enhancer element, consisting of a contiguous nucleotide sequence from about nucleotide 118,975 to about nucleotide 120,471 of SEQ ID NO:109;

(b) a first LAT insulator/boundary region, comprising a contiguous nucleotide sequence from nucleotide 8365 to nucleotide 9273 of SEQ ID NO:109, operably positioned upstream of said isolated LAT enhancer element and;

(c) a second LAT insulatory/boundary region, comprising a contiguous nucleotide sequence from nucleotide 120,208 to nucleotide 120,940 of SEQ ID NO:109, operably positioned downstream of the LAT enhancer element.

Dependent claims are further to the polynucleotide comprising (d) a first promoter region operably positioned upstream of the LAT enhancer element, and downstream of the first LAT insulator/boundary region, wherein the first promoter region comprises an HSV LAP 1 promoter that consists of a sequence region of from about nucleotide 117,938 to about 118,843 of SEQ ID NO:109; and

(e) at least a first multiple cloning region operably positioned downstream of said first LAT insulator/boundary region and upstream of said LAT enhancer element (**Claim 27)** and wherein said first multiple cloning region further comprises a nucleic acid sequence that encodes a promoter or an enhancer sequence that is expressed in a mammalian host cell (**Claim 28**); and

(f) at least a second multiple cloning region operably positioned upstream of said second LAT insulator/boundary region and downstream of said LAT enhancer element (**Claim 29**) and that said second multiple cloning region further comprises at least a first nucleic acid sequence that encodes a therapeutic agent (**Claim 30**) and that the first therapeutic agent is selected from the group consisting of a peptide, a polypeptide, a ribozyme, a catalytic RNA molecule, an antisense oligonucleotide, and an antisense polynucleotide (**Claim 31**). Also, dependent claims are to vectors or viral particles or virions that comprise the claimed HSV polynucleotide.

Coffin and Latchman teach HSV-1 virus throughout the reference which inherently reads on the claimed invention. See sequence alignments below which show that the claimed regions of SEQ ID NO:109 are a 100% match to the naturally occurring, known HSV-1 virus (as

shown in the attached GenBank references to the HSV complete genome and to the LAP promoter region, both dated 7/31/2010). Also, Coffin and Latchman teach recombinant HSV vectors (**e.g. abstract and page 8, lines 27-29**) comprising an isolated polynucleotide that comprises:

(a) an HSV LAT enhancer element, consisting of a contiguous nucleotide sequence from about nucleotide 118,975 to about nucleotide 120,471 of an HSV LAT 5 exon (**e.g. page 6, lines 1-5 and page 17, line 12-14**);

(b) a first LAT insulator/boundary region, consists of a contiguous nucleotide sequence from nucleotide 8365 to nucleotide 9273 of HSV1, operably positioned upstream of said isolated LAT enhancer element (**e.g. page 14, lines 10-26**);

(c) a second LAT insulatory/boundary region, consists of a contiguous nucleotide sequence from nucleotide 120,208 to nucleotide 120,940 of HSV1, operably positioned downstream of said isolated LAT enhancer element (**e.g. page 6, lines 1-5**);

(d) a first promoter region operably positioned upstream of said LAT enhancer element, and downstream of said first LAT insulator/boundary region, wherein said promoter region consists of an HSV LAP 1 promoter that consists of a sequence region of from nucleotide 117,938 to 118,843 of said HSV LAP1 promoter **(page 4, lines 15-16)**; and

(e) at least a first multiple cloning region operably positioned downstream of said first LAT insulator/boundary region and upstream of said LAT enhancer element (**page 6, lines 11-14, 29-37**) and wherein said first multiple cloning region further comprises a nucleic acid sequence that encodes a promoter or an enhancer sequence that is expressed in a mammalian host cell (e.g. **page 6, lines 11-14, 29-37**); and

(f) at least a second multiple cloning region operably positioned upstream of said second LAT insulator/boundary region and downstream of said LAT enhancer element (**e.g. page 16, lines 1-14**) and that said second multiple cloning region further comprises at least a first nucleic acid sequence that encodes a therapeutic agent (**page 7, lines 36-37**) and that the first therapeutic agent is a polypeptide of therapeutic use (**page 7, lines 36-37**).

Response to Arguments

Applicant's response filed 20 November 2009 have been fully considered but are unpersuasive. Applicant's response is to traverse the rejection stating:

> At page 6 of the Action, Coffin is said to disclose recombinant HSV vectors comprising an isolated polynucleotide that comprises each of the elements recited in applicants' independent claims. Furthermore, page 14, lines 10-26 of Coffin is cited as teaching "(b) a first LAT insulator/boundary region, consists (sic) of a contiguous nucleotide sequence from nucleotide 8365 to nucleotide 9273 of HSV1, operably positioned upstream of said isolated LAT enhancer element." (the Action, last sentence, Page 6).
>
> Applicants note for the record that regarding the instantly amended claims:
>
> Coffin does <u>not disclose</u> any isolated polynucleotide comprising: an HSV LAT enhancer element; and either first or second LAT insulator/boundary regions that consist essentially of, or alternatively consist of, a specific-contiguous nucleotide sequence from any one of SEQ ID NO:109, SEQ ID NO:110, or SEQ ID NO:111 operably positioned upstream or downstream of the LAT enhancer element, as now recited.

Also, Applicants argue that:

> the reference also does not teach or suggest any of the particular isolated polynucleotides of the invention as set forth in independent claims 1 and 73 that comprise "(a) an HSV LAT enhancer element that consists essentially of a contiguous nucleotide sequence from about nucleotide 118,975 to about nucleotide 120,471 of SEQ ID NO:109, SEQ ID NO:110, or SEQ ID NO: 111; (b) a first LAT insulator/boundary region that consists essentially of a contiguous nucleotide sequence from about nucleotide 8365 to about nucleotide 9273 of SEQ ID NO:109, SEQ ID NO: 110, or SEQ ID NO: 111, operably positioned upstream of the LAT enhancer element; and (c) a second LAT insulatory boundary region that consists essentially of a contiguous nucleotide sequence from about nucleotide 120,208 to about nucleotide 120,940 of SEQID NO:109, SEQ ID NO:110, or SEQ ID NO:111, operably positioned downstream of the LAT enhancer element."

Applicant's arguments have been fully considered but are not persuasive because the claims as written read on the genome of the Human Herpes virus strain 1 that was known in the art and is an identical sequence match to claimed sequence regions of the instant SEQ ID NO: 109 as referenced in the cited GenBank accession provided herein (see examples below that show an identical 100% sequence match to the corresponding sequence in the human Herpes virus strain 1 genome. Please note that since the claimed sequences read on the natural HSV-1 genome sequence, the claims do not distinguish from an isolated HSV-1 viral particle comprising a viral vector comprising the HSV-1 genome polynucleotide. Since Coffin and Latchman teach the HSV-1 strain virus, they teach the claimed invention.

Just below is HSV LAT enhancer sequence consisting of contiguous nucleotide sequence from about 8,365 to about 9,273 of SEQ ID NO: 109 which is shown in the attached GenBank reference to be a 100% match to the HSV-1 genome sequence comprising all of the claimed sequence regions.

```
                          taaat aaacacagcc gttctgcgtg tctgttcttg   8400
cgtgtggctg ggggcttata tgtggggtcc cgggggcggg atggggttta gcggcggggg   8460
gcggcgcgcc ggacggggcg ctggagataa cggccccggg ggaacggggg accggggctg   8520
ggtatcccga ggtgggtggg tgggcggcgg tggccgggcc gggccgggcc gggccgggcc   8580
gggtgggcgg ggtttggaaa aacgaggagg aggaggagaa ggcgggggcg ggggagacgg   8640
ggggaaagca aggacacggc ccgggggggtg ggagcgcggg ccgggccgct cgtaagagcc   8700
gcgacccggc cgccggggag cgttgtcgcc gtcggtctgc cggcccccgt ccctcccttt   8760
tttgaccaac cagcgccccc ccccccctc accaccattc ctactaccac caccaccacc   8820
accaccgaca cctcccgcgc acccccgccc acatcccccc ccaacccgca ccaccagcac   8880
gggttggggg tagcagggga tcaaaggggg gcaaagcggc ggggcggttc gggggggggg   8940
ggggggggcg ggaaaccaag taggcccgcc catccgcggc ccctcccggc agccacgccc   9000
ccagcgtcgg gtgtcacggg gaaagagcag aggggagagg ggagaggggg ggagagggga   9060
gagggggggga gaggggagag gggggggagag gggagagggg gggagagggg agagggggggg   9120
agaggggaga gggggggaga ggggagaggg ggggagaggg gagaggggggg gagaggggag   9180
agggggggag aggggagagg gggggagagg gggtatataa accaacgaaa agcgcgggaa   9240
cggggatacg gggcttgtgt ggcacgacgt cgtggttgtg ttactgggca aacacttggg   9300
gactgtaggt ttctgtgggt gccgacccta ggcgctatgg ggattttggg ttgggtcggg   9360
cttattgccg ttg
```

Just below is HSV-1 LAP 1 promoter sequence consisting of a sequence region from about 117,938 to about 118,843 of SEQ ID NO: 109 which is shown in the attached GenBank reference to be a 100% match to the HSV-1 genome sequence.

```
cagccacacg caagaacaga cacgcagaac ggctgtgttt atttaaataa accaatgtcg 118020
gaataaacaa acacaaacac ccgcgacggg gggacggagg ggacggaggg agggggtgac 118080
gggggacggg aacagacaca aaaacaacca caaaaaacaa ccacccaccg acacccccac 118140
cccagtctcc tcgccttctc ccacccaccc cacgccccca ctgagcccgg tcgatcgacg 118200
agcacccccg cccacgcccc cgcccctgcc ccggcgaccc ccggcccgca cgatcccgac 118260
aacaataaca accccaacgg aaagcggcgg ggtgttgggg gaggcgagga acaaccgagg 118320
ggaacggggg atggaaggac gggaagtgga agtcctgata cccatcctac acccccctgc 118380
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cttccaccct ccggcccccc gcgagtccac ccgccggccg gctaccgaga ccgaacacgg 118440
cggccgccgc agccgccgca gccgccgccg acaccgcaga gccggcgcgc gcactcacaa 118500
gcggcagagg cagaaaggcc cagagtcatt gtttatgtgg ccgcgggcca gcagacggcc 118560
cgcgacaccc ccccccgcc cgtgtgggta tccggccccc cgccccgcgc cggtccatta 118620
agggcgcgcg tgcccgcgag atatcaatcc gttaagtgct ctgcagacag gggcaccgcg 118680
cccggaaatc cattaggccg cagacgagga aaataaaatt acatcaccta cccacgtggt 118740
gctgtggcct gtttttgctg cgtcatctca gcctttataa aagcgggggc gcggccgtgc 118800
cgatcgcggg tggtgcgaaa gactttccgg gcgcgtccgg gtgccgcggc tctccgggcc 118860
```

Conclusion

No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE HIBBERT whose telephone number is (571)270-3053. The examiner can normally be reached on M-F 8AM-5PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NANCY VOGEL/
Primary Examiner, Art Unit 1636

Catherine Hibbert
Examiner AU1636